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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/174,937	10/19/98	CURTIS R	MNI.061

000959
LAHIVE & COCKFIELD
28 STATE STREET
BOSTON MA 02109

MM12/1208

EXAMINER	
BUGAISKY,G	
ART UNIT	PAPER NUMBER
1653	6

DATE MAILED: 12/08/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/174,937	CURTIS et al.
Examiner	**Group Art Unit**
Gabriele E. Bugaisky	1653

Responsive to communication(s) filed on _____

This action is **FINAL.**

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- [X] Claim(s) 1-26 is/are pending in the applicat
- Of the above, claim(s) _____ is/are withdrawn from consideration
- [ ] Claim(s) _____ is/are allowed.
- Claim(s) _____ is/are rejected.
- [ ] Claim(s) _____ is/are objected to.
- [X] Claims 1-26 are subject to restriction or election requirement.

Application Papers

- [ ] See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- [ ] The drawing(s) filed on _____ is/are objected to by the Examiner.
- [ ] The proposed drawing correction, filed on _____ is [ ] approved [ ] disapproved.
- [ ] The specification is objected to by the Examiner.
- [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - [ ] All [ ] Some* [X] None of the CERTIFIED copies of the priority documents have been
    - [ ] received.
    - [ ] received in Application No. (Series Code/Serial Number) _____.
    - [ ] received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - *Certified copies not received: _____
- [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- [ ] Notice of References Cited, PTO-892
- [ ] Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- [ ] Interview Summary, PTO-413
- [ ] Notice of Draftsperson's Patent Drawing Review, PTO-948
- [ ] Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, drawn to nucleic acids encoding a NIP2 homolog, constructs containing the nucleic acid and a recombinant method of making a protein, classified in at least class 435, subclasses 69.1, 320.1, 252.3, 254.11, 325 and 410, and in class 536, subclass 23.5

II. Claims 13-15, drawn to a NIP2 homolog classified in class 530, subclass 530.

III. Claim 16, drawn to antibodies specific for NIP2 homologs, classified in class 530, subclass 387.9.

IV. Claims 17-19 , drawn to assays and kits for detection of NIP2 homologs, classified in at least class 435, subclass 7.1

V. Claims 20-22, drawn to primers, probes and a method of detecting NIP2 homolog encoding nucleic acids by hybridization, classified in at least class 435, subclass 6 and class 536, subclass 24.5

VI. Claims 23-24 and 26, drawn to assays for detection of NIP2 homolog binding proteins, classified in at least class 435, subclass 7.4

VI. Claim 25, drawn to a method for modulating the activity of a NIP2 homolog, classified in class 435 , subclass 23.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be

made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be either purified from natural sources or made by chemical synthesis such as the Merrifield procedure.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. An antibody is encoded by an entirely different gene than the protein which the antibody recognizes. It would place an undue burden on an Examiner to examine unrelated inventions.

Inventions I and IV and I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different DNA constructs are not disclosed as useful in an assay of protein activity.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used to make a protein by recombinant means.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the

instant case the different inventions have different functions. The protein apparently has activity in regulating apoptosis, while the antibody binds to the protein; furthermore, the primary structure of a NIP2 homolog reveals nothing about the primary structure of any antibody that binds to it.

Inventions II and IV and II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used to generate antibodies for detection of the protein in tissue samples.

Inventions II and V and III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. Neither an encoded protein nor an antibody directed to that protein is disclosed as capable of use in a method of nucleic acid hybridization.

Inventions III and IV, and III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used for immunoaffinity purification of NIP2 homologs.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. A method of detecting a protein has no role in a method of detecting a nucleic acid by hybridization.

Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions has different effects. The invention of Group IV reveals the presence of a NIP2 homolog, whereas the invention of Group VI is a screening assay for a compound that binds to a NIP2 homolog.

Inventions IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions has different effects. The invention of Group IV reveals the presence of a NIP2 homolog, whereas the invention of Group VII is a screening assay for modulation of NIP2 homolog activity.

Inventions V and VI and V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. A method of detecting a nucleic acid by hybridization has no role in methods of protein biochemistry.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the

different inventions has different effects. The invention of Group VI is a screening assay for compounds that bind to a NIP2 homolog, whereas the invention of Group VII is a screening assay for modulation of NIP2 homolog activity.

If Group VI is elected, further restriction is required, between screening methods using transformed cells and screening methods using purified protein. These are methods using patentably distinct compositions, and are not to be considered an election of species.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter and their search required for any one of the Groups is not coextensive with that of another, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Gabriele E. Bugaisky, Ph.D. whose telephone number is (703) 308-4201. The Examiner can normally be reached from 7:30 AM to 1:30 PM on weekdays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

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December 3, 1999